§ 520.1263

Nematodirus, Bunostomum, Oesophagostomum), lungworms (Dictyocaulus), cattle grubs (Hypoderma), biting lice (Bovicola), and sucking lice (Linognathus, Solenoptes).

(3) Limitations. Drug is not effective against lice eggs. Conditions of constant helminth and ectoparasitic exposure may require retreatment within 2 to 4 weeks after first treatment. Do not administer to cattle within 19 days of slaughter. Do not administer to dairy animals of breeding age. Do not use in calves less than 3 months old, or in debilitated animals. Do not treat Brahman bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[53 FR 23757, June 24, 1988, as amended at 54 FR 1353, Jan. 13, 1989; 57 FR 7652, Mar. 4, 1992; 62 FR 55160, Oct. 23, 1997; 62 FR 61625, Nov. 19, 1997]

§ 520.1263 Lincomycin hydrochloride monohydrate oral dosage forms.

§ 520.1263a Lincomycin hydrochloride monohydrate tablets and sirup.

- (a) *Specifications*. The sirup contains lincomycin hydrochloride equivalent to either 25 milligrams or 50 milligrams of lincomycin.
- (b) Sponsor. See No. 000009 in $\S510.600$ (c) of this chapter.
- (c) Conditions of use. (1) The drug is indicated in infections caused by grampositive organisms which are sensitive to its action, particularly streptococci and staphylococci.
- (2) It is administered orally to dogs and cats at a dosage level of 10 mgs per pound of body weight every 12 hours, or 7 mgs per pound of body weight every 8 hours. Treatment may be continued for periods as long as 12 days if clinical judgment indicates.
- (3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 44 FR 7130, Feb. 6, 1979; 64 FR 403, Jan. 5, 1999]

§ 520.1263b [Reserved]

§ 520.1263c Lincomycin hydrochloride soluble powder.

(a) Specifications. Each gram of soluble powder contains lincomycin hydro-

chloride equivalent to $0.4~\mathrm{grams}$ of lincomycin.

- (b) Sponsors. See Nos. 000009, 046573, 054925, 059130, and 061623 in §510.600(c) of this chapter for use as in paragraph (d) of this section.
- (c) Tolerances. See §556.360 of this chapter.
- (d) Conditions of use—(1) Swine—(i) Amount. 250 milligrams per gallon of drinking water to provide 3.8 milligrams per pound of body weight per day.
- (ii) *Indications for use.* For the treatment of swine dysentery (bloody scours).
- (iii) Limitations. Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Do not use for more than 10 days. If clinical signs of disease have not improved within 6 days, discontinue treatment and reevaluate diagnosis. The safety of lincomycin has not been demonstrated in pregnant swine or swine intended for breeding. For No. 051259: Do not slaughter swine for 6 days following last treatment.
- (2) Chickens—(i) Amount. 64 milligrams per gallon of drinking water.
- (ii) *Indications for use.* For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin in broiler chickens.
- (iii) Limitations. Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Administer for 7 consecutive days. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Not for use in layer and breeder chick-

[48 FR 3966, Jan. 28, 1983, as amended at 55 FR 3209, Jan. 31, 1990; 60 FR 14217, Mar. 16, 1995; 62 FR 65020, Dec. 10, 1997; 64 FR 13341, Mar. 18, 1999; 64 FR 13508, Mar. 19, 1999; 64 FR 66382, Nov. 26, 1999; 65 FR 10705, Feb. 29, 2000; 67 FR 17284, Apr. 10, 2002; 67 FR 71819, Dec. 3, 2002; 67 FR 78356, Dec. 24, 2002; 68 FR 3817, Jan. 27, 2003; 70 FR 1818, Jan. 11, 2005]

§ 520.1265 Lincomycin and spectinomycin soluble powder.

(a) Specifications. The following salts of lincomycin and spectinomycin are present in a soluble powder in the ratio of 1 to 2 on the basis of equivalency of lincomycin base to equivalency of spectinomycin base:

Food and Drug Administration, HHS

- (1) Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate.
- (2) Lincomycin hydrochloride monohydrate and spectinomycin dihydrochloride pentahydrate.
- (b) *Sponsors.* See sponsors in §510.600(c) of this chapter for use as in paragraph (d) of this section.
- (1) No. 000009 for use of product described in paragraph (a)(1) of this section.
- (2) No. 059130 for use of product described in paragraph (a)(2) of this section.
- (c) *Tolerances.* See §§ 556.360 and 556.600 of this chapter.
- (d) *Conditions of use in chickens*—(1) *Amount.* 2 grams of antibiotic activity per gallon of drinking water; administer as the sole source of water for the first 5 to 7 days of life.
- (2) Indications for use. As an aid in the control of airsacculitis caused by either Mycoplasma synoviae or M. gallisepticum susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by Escherichia coli and M. gallisepticum susceptible to lincomycin-spectinomycin.

[69 FR 13220, Mar. 22, 2004]

§520.1284 Sodium liothyronine tablets.

- (a) Specifications. Sodium liothyronine tablets consist of tablets intended for oral administration which contain liothyronine at 60 or 120 micrograms per tablet, as the sodium salt.
- (b) Sponsor. See No. 000069 in $\S510.600$ (c) of this chapter.
- (c) *Conditions of use.* (1) It is indicated in cases of hypothyroidism in dogs.
- (2) It is administered orally to dogs at levels up to 12.8 micrograms per kilogram of body weight per day. Dosage should be adjusted according to the severity of the condition and the response of the patient. Dosage at the total replacement level (12.8µg per kilogram of body weight) should be considered for initiating therapy and then titrated downward for optimum maintenance effect. Twice daily administration is recommended.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1288 Lufenuron tablets.

- (a) Specifications—(1) Tablets containing 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron for use as in paragraphs (c)(1)(i), (c)(1)(ii)(A), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.
- (2) Flavored tablets containing 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron for use as in paragraphs (c)(1)(i), (c)(1)(ii)(A) or (c)(1)(ii)(B), and (c)(1)(iii) of this section.
- (3) Flavored tablets containing 90 or 204.9 mg lufenuron for use as in paragraphs (c)(2)(i), (c)(2)(ii)(A) or (c)(2)(ii)(B), and (c)(2)(iii) of this section.
- (4) Flavored tablets containing 135 or 270 mg lufenuron for use as in paragraphs (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.
- (b) Sponsor. See No. 058198 in $\S510.600$ (c) of this chapter.
- (c) Conditions of use—(1) Dogs—(i) Amount. Minimum of 10 mg lufenuron per kilogram (4.5 mg per pound (lb)) of body weight, once a month.
- (ii) Indications for use—(A) For the prevention and control of flea populations.
- (B) The concurrent use of flavored lufenuron tablets described in paragraph (a)(2) of this section as in paragraph (c)(1)(ii)(A) of this section with nitenpyram tablets as in §520.1510(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.
- (iii) *Limitations.* For use in dogs and puppies 4 weeks of age and older.
- (2) Cats—(i) Amount. Minimum of 30 mg lufenuron per kilogram (13.6 mg/lb) of body weight, once a month.
- (ii) *Indications for use*—(A) For the control of flea populations.
- (B) The concurrent use of flavored lufenuron tablets described in paragraph (a)(3) of this section as in paragraph (c)(2)(ii)(A) of this section with nitenpyram tablets as in §520.1510(d)(2) of this chapter is indicated to kill